

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIVIL ACTION NUMBER:

19-md-02875-RBK-JS

IN RE: VALSARTAN PRODUCTS
LIABILITY LITIGATION

TELEPHONIC STATUS and
DISCOVERY CONFERENCE
WITH RULINGS ON PLAINTIFFS'
CUSTODIAN LISTS AND
DOCUMENT REQUESTS

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
December 18, 2019
Commencing at 11:07 a.m.

B E F O R E:

THE HONORABLE JOEL SCHNEIDER,
UNITED STATES MAGISTRATE JUDGE

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1 (PROCEEDINGS held in open court before The Honorable Joel
2 Schneider, United States Magistrate Judge, at 11:07 a.m.)

3 THE COURT: Counsel, we are on the record in *In Re:*
4 *Valsartan*, Docket Number 2875.

5 We have a court reporter here so if you're going to
6 speak, please say your name, so the court reporter can
7 appropriately identify you.

8 Why don't we just start with getting the names of the
9 people on the phone. Start with the plaintiffs.

10 MR. SLATER: Good morning, your Honor. Adam Slater
11 for plaintiffs.

12 MR. HONIK: Ruben Honik for plaintiff.

13 MR. PAREKH: Behram Parekh for plaintiff.

14 MS. WHITELEY: Conlee Whiteley for plaintiff.

15 MR. STANOCH: David Stanoch for plaintiff.

16 THE COURT: Okay. Let's go to the defendants.

17 MR. GOLDBERG: Seth Goldberg for ZHP and the
18 defendants.

19 MS. LOCKARD: Victoria Lockard for Teva and the
20 defendants.

21 MR. RUBENSTEIN: Brian Rubenstein for Teva and the
22 defendants.

23 THE COURT: Is there anyone else on the phone who
24 hasn't said their name?

25 MR. STOY: This is Frank Stoy for Mylan and the

1 defendants; and Clem Trischler is also on the line.

2 MR. BLANTON: Robert Blanton for Hetero, U.S.A.

3 THE COURT: Anyone else?

4 MR. KAPLAN: This is Andrew Kaplan for Cardinal
5 Health Major Pharmaceuticals and the Harbor Drug Group.

6 MR. GEOPPINGER: Jeffrey Geoppinger for
7 AmerisourceBergen.

8 MS. NORRIS: This is Ellie Norris for McKesson.

9 THE COURT: Okay. Let's get to what we're here for.
10 One, I commend the parties for the substantial
11 progress they made.

12 I'm aware of several issues that involve ZHP. Let's
13 put those aside for the moment, and I'd like to start by just
14 dealing with and confirming where we don't have any disputes.

15 I'm going to read for the record what I think are the
16 exhibits where there is no dispute, and I would just like to
17 get confirmation from the parties.

18 It appears to the Court that there is no dispute
19 regarding the following exhibits that are attached to
20 Mr. Slater's December 17, 2019, letter, Docket Number 324:
21 Exhibit B, the ZHP custodians; Exhibit C, the Mylan
22 custodians; Exhibit D, the Teva custodians; Exhibit E, the
23 Hetero USA custodians; Exhibit F, the Aurolife and Aurobindo
24 USA custodians; and Exhibit G, the Torrent custodians. Am I
25 correct that there are no objections to those exhibits?

1 MR. SLATER: Your Honor, Adam Slater.

2 I think there is an objection to one custodian on the
3 ZHP list, Exhibit B. And I think there is no objection and no
4 dispute as to Exhibit H, the search terms.

5 THE COURT: Is that correct?

6 MR. GOLDBERG: Yes, your Honor. This is Seth
7 Goldberg on behalf of ZHP.

8 We do have one objection -- or an objection to one of
9 the custodians on the ZHP list, but, other than that, we have
10 no objection to the custodians, and I think Mr. Slater is
11 correct about the other custodian lists and the search terms.

12 THE COURT: We will add Exhibit H to the list of
13 agreed upon exhibits. Exhibit H is the search terms.

14 Let's talk about Exhibit B then and address the
15 objection that is made.

16 Mr. Goldberg, the Court will hear you.

17 MR. GOLDBERG: Thank you, your Honor.

18 And I don't know if you've had a chance, but I did
19 send you an e-mail about an hour ago on this.

20 THE COURT: I did see it and I did read it.

21 MR. GOLDBERG: Okay.

22 THE COURT: What's the gentleman's name again?

23 MR. GOLDBERG: The gentleman's name is Baohua Chen.
24 He is the highest ranking official at ZHP. He is --

25 THE COURT: Where is he on Exhibit B?

1 MR. GOLDBERG: I have to --

2 THE COURT: Oh, last page, third one down? The third
3 page --

4 MR. GOLDBERG: Yes, yes.

5 THE COURT: B-A-O-H-U-A Chen, C-H-E-N.

6 MR. GOLDBERG: Correct.

7 THE COURT: Okay. Let's hear it.

8 MR. GOLDBERG: And if you recall the org charts,
9 Mr. Chen is at the highest box on the org charts. He's the
10 highest ranking official at ZHP. He is not involved in any of
11 the manufacturing, testing, regulatory, quality affairs,
12 quality assurance, quality control functions at the company,
13 and Mr. Du explained that when he met with your Honor and
14 plaintiffs in October. He is, in addition to being the
15 president of the company, he's also chairman of the company's
16 board.

17 Mr. Du, who the Court has ordered to be a custodian,
18 is the second highest ranking official at ZHP. He's the vice
19 president. He is also the vice chairman of the board. And,
20 in our view, the production -- the custodial file of Mr. Chen
21 is not necessary because of -- that it will be cumulative and
22 duplicative with that of Mr. Du.

23 But, more importantly, perhaps, is the fact that, as
24 we previously discussed, information that's going to be
25 produced by ZHP to the U.S. has to undergo a State secret

1 review, and there are going to be various categories of
2 information that are going to be subject to the State secrets,
3 and we'll learn that as we collect the documents.

4 But one thing is clear about Mr. Chen that is
5 different than all of the other custodians, is that he is an
6 official in the Chinese government, and he serves on various
7 committees for the Chinese government. We have provided some
8 of that information to you that was readily available to us,
9 identified to us by our client just yesterday. And once we
10 learned this, we promptly communicated that to Mr. Slater and
11 plaintiffs' counsel.

12 But you can see on this document that I sent you, he
13 is currently a member of the Tenth Zhejiang Provincial
14 Committee, a member of the Third Standing Committee of the
15 Chizhou Municipal People's Congress, and a member of the 14th
16 Standing Committee of the Linghai Municipal People's Congress.

17 What we understand is in his role as a government
18 official, he obviously has communications in that role, and
19 what we don't want to do is have an already exceedingly
20 burdensome process with respect to the State secret review to
21 be even more burdensome by having to work around Mr. Chen's
22 role with the Chinese government, especially in light of the
23 fact that plaintiffs are getting the second highest official
24 of the company, the vice chairman of the board, and somebody
25 who plaintiffs have, you know, made at least -- they claim to

1 have made a good-faith basis for Mr. Du because, as they say,
2 he's attended regulatory meetings, he's attended FDA
3 inspections, and so, in addition to having board-related
4 information and management-related information, Mr. Du will
5 have information pertinent to the facts at issue.

6 Mr. Chen, at most, is going to have the
7 management-related communication and board communications
8 about valsartan, if any, and those are going to be duplicative
9 with what Mr. Du has. And so, for those reasons, we think
10 having Mr. Chen as a --

11 DIGITAL VOICE: Is now in the conference.

12 MR. GOLDBERG: -- as an ESI custodian is not
13 warranted --

14 DIGITAL VOICE: Has left the conference.

15 MR. GOLDBERG: -- and will not provide meaningful,
16 probative information that another witness or another
17 custodian won't be able to provide.

18 And, importantly, your Honor, we're not suggesting
19 that your Honor not provide a substitute ESI custodian. We
20 just think the burden is not warranted for Mr. Chen.

21 THE COURT: Mr. Slater?

22 MR. SLATER: Thank you, your Honor.

23 First of all, Mr. Chen's name appears in the core
24 discovery documents. He was copied on them and is aware of
25 what was happening. And it's our understanding from reading

1 the core discovery documents and seeing how they were drafted
2 that he would have been fully aware of everything and, thus,
3 we would expect that he was involved in decision-making,
4 number one.

5 Number two, counsel's making a representation about
6 duplicative documents when they haven't searched the documents
7 yet. And I think that goes back to the case we discussed last
8 week. They have never actually collected the documents or
9 done a comparison to be able to say there is a duplication or
10 that there aren't probative documents that would only appear
11 in one or the other's custodial files, so it's completely
12 speculative what they're telling you.

13 Number three, this entire -- really, what they're
14 really saying is the State Secrets Doctrine somehow is going
15 to make this burdensome for them. This is -- honestly, it's
16 opened a new door to another massive macro issue in this
17 litigation, and I'm very glad that it's now been uncovered and
18 put in front of us. Because from the plaintiffs' perspective
19 and I think from the perspective of the United States of
20 America and regulation of drugs, that has absolutely no
21 significance, and it should not be given any weight in
22 these -- or any consideration on this objection.

23 If they're saying because he was -- whatever he
24 was -- I don't know the meaning of what his positions were.
25 We all know many people we work with are the mayor or the

1 municipal prosecutor and they hold other jobs at other
2 businesses, so I don't know if he's the mayor. I don't know
3 what his -- the importance of it is, and it doesn't really
4 matter. If the government chooses to have him have some role
5 in the government, we now need to know -- first of all, that
6 should never be a basis to hide any information from us.
7 Number one, if it's relevant, we should get it anyway.

8 If they're going to take the position that under
9 Chinese law, we are not going to get probative information,
10 that's a macro issue that we need to have thoroughly disclosed
11 at this point in the litigation for both the benefit of the
12 parties and the benefit of the Court, because if they, for
13 example, are going to say there is some important information
14 from some custodian's file that they're not going to produce,
15 that could have a significant impact on what's going to happen
16 in discovery and what we're going to know.

17 I'm looking -- and coming back to the core discovery
18 documents, I'm looking at documents that were produced, for
19 example, a document from Baohua Chen dated September 24th,
20 2007, to the Drug Master File Staff at the FDA, and in that
21 document, he's talking about valsartan active API and
22 certifying certain information about it. I won't get into
23 more detail, but I can represent to your Honor, he was the
24 author of this letter on the drug master file to the FDA in
25 2007.

1 So, we have other documents I have in front of me, so
2 I can make a good-faith representation that there are other
3 documents.

4 I have another one going back to 2012, where
5 information is being provided about his involvement with
6 valsartan as a chemical engineer, one of his qualifications to
7 have information about this.

8 So he's factually relevant to this case. What the
9 top executive in the company knew, what that person was told,
10 what that person did, is significant both to liability on the
11 substantive claims and the punitive damages claims in this
12 case. So, you know, the buck stops with him, and he's above
13 Jun Du, and he had involvement with valsartan, so we would
14 have a very strong factual basis to include him.

15 And, again, this idea that somehow Chinese law or
16 State secrets is going to somehow impede discovery in this
17 litigation is of enormous concern, and it's a side issue
18 that's now been opened. Well, I think that ZHP needs to make
19 a representation to the Court as to the extent to which they
20 think that Chinese law, whether it's State secrets or anything
21 else, is going to impede discovery, is going to impede our
22 access to witnesses, is going to impede our ability to collect
23 a judgment at the end of the litigation. I mean, this is very
24 significant information that I think that we all need to get
25 our arms around.

1 So, for all those reasons, we ask that Mr. Chen be
2 maintained as a custodian, and I suppose at another time soon,
3 maybe in the conference, we can start to talk about how
4 Chinese law may impede our ability to vindicate our clients'
5 rights in this litigation.

6 THE COURT: Let me jump in here, Mr. Goldberg. We'll
7 hear from you, but let me just jump in here for a second.

8 Mr. Slater, I think you're raising an issue about the
9 State secret that we've touched on previously in the case,
10 although we haven't gotten into it in detail. It is an
11 enormous issue. I don't think there is any question about
12 that. But I think it's premature to deal with the issue now.

13 What I would envision is that we would handle -- if
14 there is a State secret issue, we would handle the issue akin
15 to how we would handle privileged documents.

16 If there are relevant documents that are responsive
17 to the document requests that come up in the hits with
18 custodians and the search terms, and if ZHP feels that its
19 hands are tied and it can't produce those documents because of
20 Chinese State Secrecy Law, I would assume that ZHP would
21 identify those documents akin to a privilege log, and then it
22 would be appropriate to deal with the State Secret Law. But I
23 don't know how we can deal with this State Secret Law without
24 knowing, one, whether there are any responsive documents that
25 are going to be withheld on that basis; and, two, generally,

1 what those documents are.

2 MR. GOLDBERG: Your Honor --

3 THE COURT: Mr. Goldberg, were your thoughts any
4 different?

5 MR. GOLDBERG: No. And, in fact, I think what you
6 are getting at is exactly why, one, Mr. Chen is really not a
7 proper custodian; and, two, how this issue is going to be
8 dealt with in a way that we're trying -- you know, the
9 challenge here is we expect -- given the production of
10 information we've already made, given the kind of information
11 the FDA is able to review and obtain, we know that, you
12 know -- I mean, we expect at least that quantities of
13 information are not subject to the State secret review. You
14 know, these core -- core discovery documents, for instance,
15 all of these communications, the manufacturing documents.

16 We -- what our concern is -- and so, what we hope to
17 be able to do is to have a privilege-log-type document, and,
18 hopefully, it doesn't have a huge volume of information on it.
19 We don't expect it to, given the issues in this case.

20 Mr. Chen is uniquely different because it's not his
21 relevant information, if any; it's the vast quantities of --
22 potentially vast quantities of actual government-related
23 documents in his custodial file that had nothing to do with
24 this case. That would be a burden for us to have to translate
25 and review, to determine that they are State secrets because

1 they're -- you know, they really relate to his role with the
2 government in a non-valsartan-related way.

3 THE COURT: But, Mr. Goldberg, to butt in here, in
4 theory, wasn't the purpose of identifying the search terms so
5 that the parties would avoid getting hits on irrelevant
6 documents? So, if there is a purely political document that
7 has nothing to do with valsartan, in theory, it wouldn't show
8 up on any of the searches that are done for the documents. In
9 theory, isn't the case that the only documents that would have
10 to be reviewed would be those that are responsive to the
11 search terms which are designed to identify relevant
12 documents?

13 MR. GOLDBERG: I don't disagree with you that, in
14 theory, that is correct.

15 I think the parties have chosen a very broad set of
16 search terms, over 400 of them, some of which are generic
17 terms, and the challenge here is that we're not just dealing
18 with looking at the documents. There is a cost to having to
19 translate them to determine, if a false positive is not
20 related to the case, that's one thing; if a false positive is
21 a State secret, we have to make sure of that. So, for ZHP,
22 the burden is quite different than other defendants because
23 even to make that determination, we need to spend the money
24 and the time to translate the document.

25 And so I think, with respect to Mr. Chen, given his

1 role at the company and given Mr. Du as an ESI custodian, it
2 seems that there is only marginal, if any, relevance or need
3 to have Mr. Chen as a custodian.

4 THE COURT: Let me ask you this question,
5 Mr. Goldberg, and this really gets to the crux of it. If we
6 had assurances that whatever information would come up in the
7 search of Mr. Chen is duplicative of what would come up in
8 other searches, then the Court's decision would be easy.

9 Mr. Slater cited a specific document, this letter, I
10 forgot the date, that he apparently authored about the DMF to
11 the FDA. So let's talk about that letter. Is that letter --
12 hold on, hold on.

13 MR. SLATER: Judge --

14 MR. GOLDBERG: Your Honor --

15 THE COURT: Hold on.

16 (Simultaneous indiscernible colloquy by counsel.)

17 MR. GOLDBERG: Your Honor, let's talk about this
18 letter, because as Mr. Du explained --

19 MR. SLATER: I'm sorry, Mr. Goldberg. Can I just --
20 I think it will help the call. I'm sorry.

21 I just need to read one paragraph from the letter. I
22 think it will -- it's dispositive, I think.

23 This is the September 24th, 2007, letter from
24 Mr. Chen to the Drug Master File Staff of the FDA which
25 states, in part -- and I'm quoting from the letter, and I

1 can't pronounce it well yet, give me another few years, but:
2 Zhejiang Huahai hereby certifies that valsartan API product
3 supplied under this DMF will be manufactured in accordance
4 with the methods described within, and any changes to be made
5 in the described methods will be communicated to any users of
6 this product, as well as to FDA, via filing updates. We
7 hereby authorize the FDA for any inspection of our valsartan
8 API manufacturing facility by its inspectors." And that's him
9 writing it in 2007. I apologize for interrupting, but I
10 thought this paragraph of the letter would be helpful to the
11 argument.

12 THE COURT: Mr. Slater --

13 MR. GOLDBERG: Your Honor --

14 THE COURT: Hold on one --

15 MR. GOLDBERG: Your Honor, this document -- sorry, go
16 ahead.

17 THE COURT: I was just going to ask, what was
18 Mr. Chen's position when he wrote that document?

19 MR. SLATER: It says, General Manager -- it says,
20 General Manager, ZHP Limited. So, apparently, he carried
21 multiple titles over the years.

22 THE COURT: So --

23 MR. GOLDBERG: Whatever that title was, it is --

24 (Simultaneous indiscernible colloquy by counsel.)

25 MR. GOLDBERG: Whatever that title was, it is the

1 functional equivalent of the president title that he holds
2 now. That document is completely irrelevant to any of the
3 manufacturing-related issues here. He certified a letter. He
4 didn't author the letter.

5 (Simultaneous indiscernible colloquy by counsel.)

6 MR. GOLDBERG: -- is required to be made of the
7 management of every pharmaceutical company. It's like a CFO
8 certifying an SEC filing or any other kind of government
9 filing. It doesn't suggest that Mr. Chen has any involvement
10 with any of the manufacturing, testing, quality control,
11 quality assurance, or regulatory facts at issue. And, in
12 fact, that document predates the relevant time period.

13 There is nothing produced with respect to the
14 current -- the current manufacturing process, the regulatory
15 issues, relating to the recall, any of the testing.

16 And Mr. Du, your Honor, explained that to plaintiffs
17 in court, and he explained that Mr. Chen has no involvement in
18 any of this. It's a stretch to think that Mr. Du does, and --
19 simply because he's been on these documents, but he has been
20 at the inspections. He has been involved in the inspections.
21 That's apparent. But plaintiffs have not made -- the simple
22 fact, as your Honor said, some involvement in valsartan is not
23 the standard. Your Honor said that last week. At most, a
24 letter signing -- signing a foreign letter is some
25 involvement.

1 THE COURT: Here is my question.

2 MR. GOLDBERG: That's at most.

3 THE COURT: Here's my question, Mr. Goldberg. This
4 is the crux of it. The first part of what I said had to do
5 with the privilege issue. It just seems to me that what the
6 Court said is really not debatable. It's an issue. The State
7 secret concern is an issue. If ZHP withholds relevant
8 responsive documents on the basis of State secret, those
9 documents or documents have to somehow be identified on
10 something akin to a privilege log, and then we can decide the
11 issue.

12 The Court is unable to decide whether or not the
13 privilege protects documents without knowing, one, whether
14 there is even an assertion of a State secrets privilege,
15 that's what I'm calling it, or what the documents are.

16 The second issue which I think really gets to the
17 crux of this is: The key 2007 document that Mr. Slater is
18 citing to, Mr. Chen signed it. Would that document be
19 produced, identified --

20 MR. GOLDBERG: Yes.

21 THE COURT: -- if we take him off the --

22 MR. GOLDBERG: It was produced. That document would
23 have shown up in the search terms. It was produced because
24 it's part of the regulatory file.

25 Remember, Mr. Du's custodial file is going to be

1 produced. To the extent that Mr. Du, at the second highest
2 ranking management level in the company, received information
3 about any of the manufacturing processes at issue, that stuff
4 is going to be produced. All of the valsartan information is
5 going to be produced.

6 I mean, the idea that Mr. Chen has received a
7 communication that no one else at the company has received
8 relating to valsartan or somehow wrote -- maybe his own
9 document, that no one else has seen, relating to valsartan,
10 that's what you're -- that's how you would weigh the burden.
11 The chance that Mr. Chen has a document that no one has seen
12 before that has to do with valsartan, in his role as the
13 highest ranking official, versus the burden of searching
14 through all of his documents, translating them, to ensure that
15 they don't contain State secrets about his role with the
16 Chinese government, in various roles.

17 THE COURT: Mr. Slater, last word. Isn't that the
18 key question the Court has to consider: What is the
19 likelihood that something is going to be turned up with
20 Mr. Chen listed as a custodian that is not otherwise revealed
21 or produced, given the scope of the custodian list and the
22 search term list? What is that likelihood?

23 MR. SLATER: The case that we talked about last
24 week -- I don't have it in front of me -- was very clear. All
25 the defense is saying is this is what we think is going to

1 happen. They've never done what that case said you have to do
2 which is actually review the custodial file and be able to
3 tell the Court there is complete duplication. I'm not in
4 their files. This person -- the fact that this document was
5 in the core discovery -- I'm being presented with a moving
6 target, frankly.

7 I was asked why -- the start for Mr. Goldberg was he
8 had no involvement whatsoever. Let's remember where we
9 started. This man had nothing to do with valsartan at all.
10 So I had Chris Geddis running down the hall, pulling documents
11 out of the core discovery, and running back into the room with
12 these documents to show, yes, he had involvement. And this is
13 not a form. It doesn't say he's certifying someone else's
14 information. It's signed "sincerely" by him. So we
15 established what Mr. Goldberg said we couldn't, that this
16 person was involved with valsartan.

17 Now he's saying, well, also, we think you're not
18 going to get anything different from him, but we've never
19 collected his documents, we've never compared his custodial
20 file to anybody else.

21 And, by the way, we have proofs we have to make,
22 Judge. We have to take this as high as we can to prove
23 punitive damages, and to prove the absolute liability.

24 He's the person who represented to the FDA that the
25 core issue in this case, that any changes would be

1 communicated to any users of the product, which we know did
2 not occur. So he specifically represented to the United
3 States of America Food and Drug Administration that something
4 would happen that did not occur, and we don't believe that the
5 full scope of this was disclosed. I don't know what else is
6 in his file by way of notes, worksheets, meeting notes, of
7 committees that he may have sat on that other custodians may
8 not have sat on. We have no idea. But there is enough of a
9 good-faith basis, because, again, their objection was that
10 this person did not -- here -- far removed from day to day,
11 unlikely to have materially relevant documents. We have
12 proven that that objection is unfounded. That was their
13 objection. They have no basis to say they've compared
14 custodial files.

15 It is common, in every case I've ever been involved
16 in, for the chief executives of the company to have their
17 files searched so we can see what their involvement was, what
18 instructions they gave, were they misled. We don't know any
19 of those things, and we have to be able to make a case that
20 right up to the very top of the company, there is liability.

21 THE COURT: All right. The Court's prepared -- the
22 Court's prepared to rule.

23 DIGITAL VOICE: Is now in the conference.

24 THE COURT: The Court is prepared to rule on the
25 issue, and I'll explain the reasons for the Court's decision.

1 The Court's decision is that at this time, it is
2 going to sustain Mr. Goldberg's objection and remove Mr. Chen
3 as a custodian on the exhibit to be approved by the Court.

4 The reason for the Court's ruling is because it
5 perceives the key issue to be asked is what is the likelihood
6 that documents are going to be revealed in Mr. Chen's search
7 that are not going to be revealed by all the other custodians
8 and search terms?

9 We don't know, of course, to a certainty that
10 Mr. Chen does not have unique documents. We have to apply our
11 common sense and experience to reach a judgment on that issue.
12 The Court's common sense and experience on that issue tells me
13 that a person at the top of the food chain gets information
14 fed by other people to it, certainly, the number two person,
15 Mr. Du.

16 The Court just does not believe at this time, based
17 on the present record, that a search of Mr. Chen's custodial
18 files will add any material evidence or documents that are not
19 otherwise going to be proven in the case.

20 With regard to the burden issue, quite frankly,
21 that's not a big factor in the Court's decision. This case is
22 enormous. The potential damage claim in this case is
23 enormous.

24 On top of that, when the Court considers the burden
25 to the parties, the Court takes into account the public

1 interest. There is tremendous public interest in this case.
2 It has enormous public health consequences -- whether a very
3 popular drug supplied in the United States was contaminated or
4 not. Given the public interest and the health and welfare
5 implications, when it comes to evaluating the burden to the
6 defendant in the case, the Court has to take that into
7 consideration. It's not just a simple matter of dollars and
8 cents, but on this particular issue, it really isn't a dollar
9 and cents issue as far as the Court's concerned.

10 The Court's main concern is, again, whether or not,
11 if we add this person to a pretty hefty custodian list, it's
12 likely or probable that we're going to find something that is
13 not otherwise going to be produced. I don't think that's the
14 case. I could be proven wrong in the future. If there is
15 evidence in that regard, so be it.

16 But in terms of a custodian search for documents, the
17 Court sustains Mr. Goldberg's objections and will remove
18 Mr. Chen from the list, and will approve the list absent his
19 name.

20 I'll make it clear. The Court is not ruling at this
21 time whether or not Mr. Chen is an appropriate deponent.
22 That's a completely different evaluation that the Court has to
23 consider at the relevant time. If defendant wants to depose
24 Mr. Chen, we'll deal with the issue at that point. But in no
25 way, shape, or form should the Court's ruling as to whether or

1 not Mr. Chen is an appropriate custodian be deemed as a ruling
2 as to whether or not he may be deposed in the case.

3 So that's the Court's ruling as to Mr. Chen. I'm
4 going to approve Exhibit B with the removal of his name from
5 the list.

6 MR. SLATER: Your Honor, we need to substitute
7 somebody for him.

8 THE COURT: Do you have a name?

9 MR. SLATER: I would need a couple hours or an hour
10 or two just so I can talk to somebody, to some people, and
11 just figure out who to substitute.

12 THE COURT: Okay. Could you e-mail me that name,
13 Mr. Slater, and I'll add it to Exhibit B, so I can enter this
14 order?

15 MR. SLATER: Of course.

16 THE COURT: Thank you.

17 All right. Is the only issue left the issues
18 regarding the document requests?

19 MR. SLATER: Your Honor --

20 MR. RUBENSTEIN: Your Honor, very quickly, this is --
21 sorry. This is Brian Rubenstein for the Teva defendants.

22 There is no objections with respect to Exhibit D, the
23 list of Teva custodians, but there were just a few names that
24 were misspelled, so we can submit a revised list with the
25 proper spellings of those few names.

1 THE COURT: Okay. Would you be kind enough to e-mail
2 that to me so that I can enter this before the holiday? Or
3 fax it?

4 MR. RUBENSTEIN: Yes.

5 THE COURT: You could e-mail it or fax it?

6 MR. RUBENSTEIN: Yeah, e-mail. E-mail would be
7 easier. That's no problem.

8 THE COURT: Thank you, counsel.

9 MR. RUBENSTEIN: Yep.

10 THE COURT: With regard to the requests for
11 documents, should the Court be looking at Exhibit A-1?

12 MR. SLATER: Whatever is easier for your Honor to
13 read.

14 And before you even start, we can tell you there was
15 a couple other things that happened after we sent it in to
16 clarify a couple of the issues, so there is a couple of things
17 that will get us closer to the finish line.

18 THE COURT: Okay. Let's deal with the issues, and
19 you can send me a clean version so I could get it entered.

20 So I have the letter. I'm on Page 2 of the letter.
21 Should we start with Number 19?

22 MR. SLATER: Sure.

23 THE COURT: Okay. What's the dispute?

24 MR. SLATER: The defendants have asked to take out
25 the word "all." It's obviously a significant term in the

1 request, and it was not objected to, so we believe it should
2 be left as it is. To leave it as produce documents with
3 regard to the manufacturing process could mean produce a
4 couple of documents. We want all the documents that come
5 within the scope of what was heavily and detail argued last
6 week, and there was no objection to the word "all" last week
7 because it was recognized as necessary.

8 THE COURT: Do you want to be heard, Mr. Goldberg?

9 MR. GOLDBERG: I mean, you know, your Honor, I'm just
10 looking at the transcript from the hearing we had, where we
11 talked about Request 19, and Page 23 of that transcript starts
12 with me saying for Number 19, "We will produce documents
13 regarding," and then there is a whole list of documents.
14 They're going to get these documents.

15 I think when you use the term "all documents
16 regarding," that kind of breadth is exactly what we've been
17 meeting and conferring about for three months. Of course,
18 they're going to get the documents, and they're all listed
19 there.

20 THE COURT: The word "all," the Court rules the word
21 "all" stays in. Mr. Goldberg's concern is dealt with because
22 the request specifically refers to the documents on the
23 December 11 transcript, so I think the concern of the
24 defendants is taken care of.

25 Number 20?

1 MR. SLATER: The same issue, your Honor.

2 THE COURT: Stays in.

3 Number 21?

4 MR. SLATER: This issue was -- and it might be
5 helpful just because the red line may cross out the language
6 and be hard to read, but if you recall at the hearing,
7 Mr. Trischler asked us to put in the specific language from
8 the macro order by your Honor on this testing question to
9 provide more specifics on the scope of what needed to be
10 produced, and so we put that language in there. So we thought
11 that we were complying with the request, which made some
12 sense, because it gives more meat to what the request is
13 getting at, and so we're unsure as to why now the position is
14 that language should not be there, when we were asked to
15 include it and agreed to at the hearing.

16 THE COURT: Which is the language that's the subject
17 of the dispute?

18 MR. SLATER: It's -- you can see a lot of it is
19 crossed out, but after the word "Docket 303" in the third
20 line --

21 THE COURT: Yes.

22 MR. SLATER: -- and I'm reading from the clean
23 version, it says: As stated in the Court's November 25, 2019,
24 order, this includes tests showing unknown and unidentified
25 testing peaks or general toxic impurities in valsartan API or

1 valsartan, any tests that could identify the presence of
2 nitrosamine contamination, and testing and results regarding
3 other carcinogens, general toxic impurities, or residual
4 solvents in the valsartan API and valsartan. That is --

5 THE COURT: Okay.

6 MR. SLATER: That is the language that they're
7 objecting to.

8 THE COURT: Anyone want to speak to that for the
9 defendants?

10 MR. GOLDBERG: Your Honor, I think -- I think we've
11 already struck it, or primarily struck it, simply because it's
12 duplicative of the first sentence, which expressly
13 incorporates Paragraph 8.

14 THE COURT: The Court's ruling is --

15 MR. GOLDBERG: It --

16 THE COURT: I'm sorry.

17 The Court's ruling is that the language stays in. It
18 simply quotes the Court's transcript. There is no debate
19 about it. It doesn't hurt anyone. So it stays in.

20 Number 44.

21 MR. GOLDBERG: Your Honor, before you move on, there
22 is another edit to this paragraph.

23 THE COURT: Okay.

24 MR. GOLDBERG: It says -- in the last sentence, it
25 says: As ordered during the December 11th court hearing, the

1 relevant time period for ZHP's production of the testing
2 listed in plaintiffs' December 10, 2019, letter shall date
3 back to the start of the implementation of the manufacturing
4 process in 2007 for ZHP and to the date on which the
5 manufacturing process was first implemented for other API
6 manufacturers.

7 I don't think the last part was ruled on. I don't
8 know that the Court made that ruling, that testing would go
9 back to the date first implemented for other API
10 manufacturers. And with respect to ZHP, I think the
11 discussion in court was about chromatograms and chromatography
12 because that is the kind of testing that the parties have
13 agreed can be used to identify impurities.

14 THE COURT: Let me just talk to that last issue you
15 raised. It was not the Court's intent to limit the responsive
16 testing to just that one test, Mr. Goldberg. I don't know,
17 I'm not an expert on tests, but if there is unknown testing
18 peaks or general toxic impurities in a valsartan test besides
19 chromatograph, it's responsive. So the last part of your
20 statement I'm very confident we dealt with, and it's not so
21 limited.

22 I agree with you that we did not specifically discuss
23 whether this particular request should go back to the start of
24 the manufacturing process for other defendants. I agree with
25 you, we only discussed it in the context of ZHP, but if I

1 recall, I could be wrong about this, when we went over the
2 relevant times, it was so close, that's my recollection of it.

3 Mr. Slater, what do you have to say about this?

4 MR. SLATER: It was my understanding -- we obviously
5 argued this in the context of ZHP because that was -- that was
6 the defendant that we went back and forth with, and we were
7 able to establish the list in the December 10 letter. But my
8 understanding was that the same reasoning should hold true for
9 the other manufacturers because we need to see what their
10 testing showed over the course of time, so the same rationale
11 would apply to the other API manufacturers as well.

12 MR. GOLDBERG: Your Honor, this is Seth Goldberg.

13 I'm going to defer to the other manufacturers, but I
14 will say that the rationale for ZHP was something very
15 specific. Plaintiffs argued that there was one process
16 before -- in 2007, that that process underwent a change in the
17 2011 through '13 time frame, and that what they wanted to be
18 able to demonstrate with respect to ZHP was what happened with
19 respect to the change in process. That was a very specific
20 issue, and did not -- at no point during that discussion was a
21 similar process discussed with respect to the other
22 manufacturers or the need for their relevant time period to be
23 enlarged. But I'm just reminding the Court of the rationale
24 as to ZHP and will defer to my colleagues.

25 THE COURT: Here is the Court's ruling on this issue.

1 We identified the relevant time periods. It's in the Court
2 order. The Court order said for good cause, we can go back
3 further. This particular request, if it's not the most
4 important document request in this set, is certainly in the
5 top two or three. So the Court rules that it's appropriate to
6 go back to the start of the manufacturing process for each of
7 the API manufacturers, even if -- and I don't know if it's the
8 case -- even if plaintiff cannot establish in the first
9 instance that there was a manufacturing change. That should
10 not be a prerequisite to the requirement to produce testing
11 results that may put the defendants on notice of a problem
12 with valsartan. So the language in 21 stays.

13 44?

14 MR. GOLDBERG: Your Honor, this is Seth Goldberg.

15 We proposed having this be qualified by Paragraph 8
16 of the Court's macro discovery order, and we proposed
17 including language to make that explicit.

18 MR. SLATER: That's fine, your Honor. We'll agree to
19 that.

20 THE COURT: Okay. The addition stays.

21 Next is 52 to 65.

22 MR. SLATER: All we did in our letter, your Honor, is
23 just qualify. It's our understanding that the qualification
24 added by defense counsel was intended to reference the Court's
25 macro discovery decision on the scope of foreign regulatory

1 discovery. If that's the intent, then we have no objection.

2 MR. GOLDBERG: That limitation or that -- you have
3 that correct, Mr. Slater, but, also, the Court's order with
4 respect to health effect issues.

5 MR. SLATER: That would obviously apply, so, you
6 know, anything that defense counsel or the defendants would
7 produce, obviously, is subject to the Court's order, so there
8 would be no basis for us to object to that. I think it's
9 already implicit. So, if that's the qualification, then we
10 can accept that.

11 THE COURT: Okay. 110 to 111.

12 MR. SLATER: Your Honor, I'm going to hand this off,
13 but I just wanted to let the Court know there has been some
14 more discussion between the parties, so I think that there is
15 going to have to be some more modification, but I'm going to
16 hand off to Ms. Whiteley now to explain what -- because I know
17 there's been meet and confers going on through this morning
18 just before the call.

19 MS. WHITELEY: Your Honor, this is Conlee Whiteley,
20 and I'm not sure if Mr. Trischler is still on the line,
21 because I know he had several commitments this morning, but he
22 and I spoke this morning, and we agreed to eliminate all of
23 the strike through in exchange for a certain qualification
24 added to Number 107 to reflect the entirety of the Court's
25 rulings.

1 THE COURT: If it's okay with you, Ms. Whiteley, it's
2 okay with the Court. If it's okay with you and Mr. Trischler,
3 it's okay with the Court. That's what I meant to say.

4 MS. WHITELEY: I understand. Thank you.

5 MR. STOIY: Your Honor, this is Frank Stoy for Mylan.
6 Mr. Trischler did have to drop off the call. But what
7 Ms. Whiteley represented is consistent with the conversations
8 that she and Mr. Trischler had this morning, with the one
9 caveat that I'm not sure the other manufacturing defendants
10 have had the opportunity to chime in, but we don't anticipate
11 that there will be any issues.

12 THE COURT: And, last but not least, Number 118.

13 MR. SLATER: We are agreeing to remove that, your
14 Honor. There were discussions that were going on that I was
15 not aware of at the time we submitted this, where it was
16 agreed by a number of our Executive Committee to remove that
17 request, so we'll remove it.

18 But there is one we skipped, which is 100, also.

19 THE COURT: Oh, 100. I'm sorry.

20 MR. GOLDBERG: Number 100 we skipped over.

21 THE COURT: Yes, I did skip 100. Excuse me. Let me
22 get to it.

23 Okay. What is the issue with 100?

24 MR. GOLDBERG: Your Honor, we --

25 MR. SLATER: I apologize. Go ahead.

1 MR. GOLDBERG: I think we had proposed revising this,
2 just to make it read consistent with the Court's -- or the
3 discussion on -- at the hearing, to have it be limited to just
4 say acting as a class representative, and to remove the
5 specific references to MS- -- to MSP Recovery Services and
6 assignors and the specific names with these.

7 At the hearing we discussed that it's just the named
8 class representatives in the three master complaints, and we
9 think having the additional names is not necessary.

10 THE COURT: The names that you want to strike, are
11 they class reps?

12 MR. GOLDBERG: Well, I don't believe the assignors
13 are, and --

14 THE COURT: Okay.

15 MR. GOLDBERG: I don't know for sure if these
16 entities are, but I think by just saying class
17 representatives, we limit it to the right universe.

18 THE COURT: That's hard to argue with -- right.
19 Mr. Slater, that's hard to argue with. What do you think?

20 MR. SLATER: Well, these are entities, the assignors
21 and the other entities that are named, they're specific,
22 they're insurers, and if they've had communications directly
23 with the defendants that are named in this, those would be
24 important.

25 The MSP itself would likely not have those -- any

1 extensive communications or it would not have the entirety of
2 communications, I should say. It is likely or a potential
3 that there will be other communications, and they would be
4 with these other entities, and the case is going to be proven
5 through documents and information from these other entities,
6 on whose behalf MSP has brought this litigation. So it's very
7 important, and it helps to build the case on behalf of MSP.
8 There is no other way to capture it. If this comes out, then
9 relevant communications will be lost from us.

10 MR. GOLDBERG: Your Honor, I think the issue here is
11 we don't -- we don't know who the assignors are. I don't know
12 that we have -- if plaintiffs are not willing to provide a
13 list or identify them, how can we know? And so why -- this
14 puts a burden on us to do something that we don't know we can
15 do.

16 THE COURT: Let me chime in here, Mr. Goldberg.

17 MR. GOLDBERG: Yeah.

18 THE COURT: We'll limit the request to just the named
19 class reps. My recollection is that there was a significant
20 number of assignors. If plaintiffs need the communication,
21 it's their client. They should ask their client for it. So
22 we will just limit it to the class reps.

23 MR. SLATER: Understood. We will modify that, your
24 Honor.

25 THE COURT: Any other issues?

1 MR. SLATER: None for plaintiffs.

2 THE COURT: So where we're left with, the Court is
3 going to get a revised copy of the document requests, and
4 we're going to get the one additional name of the ZHP
5 custodian, and we're going to get a revised list to correct
6 the typos, I think, from Mylan. And then after that, I'll
7 enter the order approving these exhibits.

8 I can't commend the parties enough for all the work
9 they did. My goal was to get this done before Christmas so
10 that at least I wouldn't feel guilty requiring the parties to
11 work over Christmas vacation.

12 If we're going to talk this afternoon on that
13 non-manufacturing defendant issue, we'll deal with it.
14 Everyone's going to be treated fairly, Mr. Slater. You don't
15 have to be worried about that. But I want to do whatever I
16 can to avoid at least this Court requiring anyone to work over
17 the holiday. So I'm glad we put in the extra effort to get
18 this done before the holiday, and, hopefully, the people who
19 have been working so hard on this can relax a little bit and
20 get back to the grindstone after the new year.

21 So I'll get those exhibits, I'll enter the order.
22 For the good of the order, anything else we need to discuss on
23 this call?

24 MR. SLATER: Nothing for plaintiffs.

25 Thank you very much for your hard work on this, too,

1 your Honor. We appreciate it.

2 MR. GOLDBERG: Your Honor, I think there is just one
3 thing we would like to clarify.

4 Your Honor had previously had defendants producing
5 documents produced to or shown to the FDA during inspections
6 and EIRs, 483s, et cetera, for finished dose facilities in
7 December -- on December 31st. At the hearing last week, we
8 discussed moving that to January 31st. I think your Honor
9 made that order or suggested he was going to make that order,
10 and I don't think we got that clarity.

11 THE COURT: Okay.

12 MR. GOLDBERG: So we would just like to have that
13 formally extended to January 31st.

14 THE COURT: Mr. Goldberg, if I didn't do that, it was
15 an oversight. Refresh my recollection about what order we're
16 talking about.

17 MR. GOLDBERG: So Docket 303 at Page 2 requires the
18 production of documents produced to or shown to the FDA during
19 inspections of the manufacturing facilities.

20 THE COURT: All right. That's good enough for me.
21 I'll take care of it, Mr. Goldberg.

22 MR. GOLDBERG: Okay.

23 THE COURT: I'll enter a new order. We'll extend
24 that date from December 31st to January 31st. If it wasn't
25 done, it was an oversight. I'll take care of it.

1 MR. GOLDBERG: Thank you, your Honor.

2 THE COURT: If I don't speak with everyone, I hope
3 you have a great holiday. Again, thank you for all your hard
4 work and we're adjourned.

5 MR. SLATER: Thank you, your Honor.

6 MR. GOLDBERG: Thank you, your Honor.

7 MS. WHITELEY: Thank you, your Honor.

8 (The proceedings concluded at 12:07 p.m.)

9 - - - - -

10

11 I certify that the foregoing is a correct transcript
12 from the record of proceedings in the above-entitled matter.

13

14 /S/ Carol Farrell, NJ-CRCR, FCRR, RDR, CRR, RMR, CRC, CRI
15 Court Reporter/Transcriber

16 December 27, 2019
17 Date

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